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10/629,048

07/28/2003

Stuart Brown

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

STOUT, MICHAEL C

ART UNIT

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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/629,048	Applicant(s) BROWN, STUART	
	Examiner MICHAEL C. STOUT	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/14/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-23 and 26-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/629,048 filed on 07/14/2009 and is a first action based on the merits of the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/2009 has been entered.

Claims 1-16 have been canceled. Claims 17 and 20 have been amended.
Claims 31-40 are new.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-23 and 26-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 17, the claim recites the limitation of the chamber comprising a volume of less than 1.2 millimeters, and it is unclear how a volume is defined by a linear dimension.

The claim further recites the device comprising “a plurality of controllable tissue sampling devices” and in line 13 further recites “contacting a sampling device”. It is unclear whether the “a sampling device” is in reference to one of the plurality of controllable tissue sampling device or an additional sampling device.

Furthermore, the scope of the claim cannot be determined because the relationship between the plurality of sampling device and the isolated chamber is unclear, because it is unclear whether there are multiple chambers or a single chamber and the chamber(s) is association with “a plurality of controllable tissue sampling devices” and in line further recites “contacting a sampling device”. The claim recites each of said sampling devices comprising *an isolated chamber*. It is unclear whether each chamber shares an (single) isolated chamber or whether each sample chamber comprises an (individual corresponding) isolated chamber.

Regarding claim 20, the scope of the claim cannot be determined because the relationship between the plurality of sampling device and the isolated chamber is unclear, because it is unclear whether there are multiple chambers or a single chamber and the chamber(s) is association with “a plurality of controllable tissue sampling

Art Unit: 3736

devices” and in line further recites “contacting a sampling device”. The claim recites each of said sampling devices comprising *an isolated chamber*. It is unclear whether each chamber shares an (single) isolated chamber or whether each sample chamber comprises an (individual corresponding) isolated chamber.

The claim further recites the device comprising “each sampling device comprising an isolated chamber” and in line 11 further recites “a local chamber”. It is unclear whether the “a local chamber ” is in reference to the previously recited sample chamber or one of a plurality of initial corresponding isolated chamber.

Claim 21 recites the limitation "the extracting device" in claim 20. There is insufficient antecedent basis for this limitation in the claim.

Should the Applicant have any questions regarding the above rejections the, Applicant is invited to contact the Examiner at the contact information below to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Claim Objections

Claim 27 is objected to because of the following informalities: Claim 27 is an improper dependent claim because it is dependent upon canceled claim 1. Appropriate correction is required. Claim 27 will be interpreted as being dependent upon claim 20.

Claim 17 is objected to because of the following informalities: Claim 17 recites “contacting a sampling device with deployment signal, said signal...,” with deployment

Art Unit: 3736

signal" should be replaced with, "with a deployment signal." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 3736

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19, 28, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr (US 6,280,450 B1) in view of Kieturakis (US 6,794,626).

Regarding claim 17, McGuckin teaches method of extracting multiple tissue samples from a subject, comprising inserting into the a volume of a tissue (see Figures 5-10) an instrument comprising a sharp distal end (65, see Figure 1 and, 205) and a plurality of controllable tissue sampling devices (206, cutting blades 50) each of said devices being located in a different position in an array along a longitudinal axis of a housing (each of the sampling devices extend along the axis of the device and are arranged in a circular array around the longitudinal axis, see Figures 1-5), each of said sampling devices comprising an isolated chamber (a membrane 30 is positioned between the shaft 20 and a tubular recovery sheath 25), the volume of said isolated chamber being less than 1.2 millimeters (the inner surface of the membrane slidably facingly contacts the outer surface of the shaft 20 prior to deployment, see Column 6, Lines 5-10); contacting a sampling device with deployment signal, said signal being selected from the group consisting of an electrical, optical, pneumatic, hydraulic, RF-transmitted, inductive, magnetic, thermal or sonic signal, said signal causing an opening of said chamber (relative movement of the tubular member 20 causes the flexible

Art Unit: 3736

blades 55 to expand during which an electrical signal is applied, see Column 6, Line 60 through column 7, line 13) removing tissue samples from an anatomical locations at varying depths within said tissue and sealing said chamber (the membrane encloses tissue samples from varying depths which are severed as the cutting blades expand, creating an enclosed space).

McGuckin fails to teach the expansion of the sampling elements resusing from a deployment signal being selected from the group consisting of an electrical, optical, pneumatic, hydraulic, RF- transmitted, inductive, magnetic, thermal or sonic signal.

Kieturakis teaches a biopsy apparatus wherein a hydraulic sources applies a pneumatic/hydraulic signal to deploy the cutting elements, see at least Columns 6 and 7 and Figures 9 and 10.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by McGuckin to include pneumatic/hydraulic actuator as taught by Kieturakis in order to move the cutting member expansion member.

Regarding claim 18, McGuckin further teaches the method, wherein said sampling devices are deployed simultaneously (see Figure 4).

Regarding claim 19, McGuckin further teaches the method, wherein each of said sampling devices is deployed temporally (see column 6, Lines 25-53, the device is also removed from the patient after tissue collection).

Regarding claim 28, McGuckin further teaches the method, wherein the volume of said isolated chamber is selected from the group consisting of 0.005, 0.01, 0.05, 0.1,

Art Unit: 3736

0.5, and 0.75 cubic millimeters (the membrane's inner surface is in contact with the outer wall of the shaft 20).

Regarding claims 33 and 35, McGuckin further teaches the method, wherein said tissue comprises a diseased area/a tumor (subcutaneous abnormal tissue, breast tissue lesion, see background sections).

Claims 20, 21, 27, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr (US 6,280,450 B1) in view of Hogendijk et al. (US 6,695,787 B2).

Regarding claims 20 and 21, McGuckin teaches method of extracting multiple tissue samples from a subject, comprising inserting into the a volume of a tissue (see Figures 5-10) an instrument comprising a sharp distal end (65, see Figure 1 and, 205) and a plurality of controllable tissue sampling devices (206, cutting blades 50) each of said devices being located in a different position in an array along a longitudinal axis of a housing (each of the sampling devices extend along the axis of the device and are arranged in a circular array around the longitudinal axis, see Figures 1-5), each of said sampling devices comprising an isolated chamber (a membrane 30 is positioned between the shaft 20 and a tubular recovery sheath 25), the volume of said isolated chamber being less than 1.2 milliliters (the inner surface of the membrane slidably facingly contacts the outer surface of the shaft 20 prior to deployment, see Column 6,

Art Unit: 3736

Lines 5-10); heating the plurality of sampling devices by passing electrical current, such that a mechanical portion of the sampling devices collects samples from varying depths within said tissue and retains the samples (relative movement of the tubular member 20 causes the flexible blades 55 to expand during which an electrical signal is applied for cauterization resulting in heading, see Column 6, Line 60 through column 7, line 13) removing tissue samples from an anatomical locations at varying depths within said tissue and sealing said chamber (the membrane encloses tissue samples from varying depths which are severed as the cutting blades expand, creating an enclosed space), removing the instrument from the subject (the device is removed at the end of the procedure).

Hogendijk teaches a method of inserting an expandable medical device into the body wherein heating causing actuation of a mechanical portion of the expandable elements, see Column 5, Lines 22-35.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by McGuckin to include Nitinol expandable elements as taught by Hogendijk in order to provide shape memory material that achieves a predetermined shape when placed in an expanded configuration allowing different excise volumes.

Regarding claim 27, McGuckin further teaches the method, wherein the volume of said isolated chamber is selected from the group consisting of 0.005, 0.01, 0.05, 0.1, 0.5, and 0.75 cubic millimeters (the membrane's inner surface is in contact with the outer wall of the shaft 20).

Art Unit: 3736

Regarding claims 34 and 36, McGuckin further teaches the method, wherein said tissue comprises a diseased area/a tumor (subcutaneous abnormal tissue, breast tissue lesion, see background sections).

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Response to Arguments

Applicant's arguments with respect to claims 17-40 have been considered but are moot in view of the new ground(s) of rejection.

Again as stated above the Applicant is invited to contact the Examiner at the contact information below to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736